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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,139	10/14/2003	Steve Mitchell	KLYC-1075US1	4489
7590 11/29/2005			EXAMINER	
Sheldon R. Meyer FLIESLER DUBB MEYER & LOVEJOY LLP Four Embarcadero Center Fourth Floor San Francisco, CA 94111-4156			HOFFMAN, MARY C	
			ART UNIT	PAPER NUMBER
			3733	
DATE MAILED: 11/29/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/685,139	Applicant(s) MITCHELL, STEVE	
	Examiner Mary Hoffman	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-81 is/are pending in the application.
4a) Of the above claim(s) 70-76 and 78-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-69 and 77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/19/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-69 and 77), Species A (FIGS. 3A-3C) in the reply filed on 10/25/2005 is acknowledged.

Claims 70-76 and 78-81 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/25/2005.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: ref. #'s 346 and 510. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the

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examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The abstract of the disclosure is objected to because the abstract is not within the range of 50 to 150 words. Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Objections

Claims 6 are objected to because of the following informalities:

In claim 6, line 2, "the S1 and L5 vertebrate" should be changed to "an S1 and an L5 vertebra," because the term "the" is used as a modifier of limitation already introduced in the claims. When first introducing limitations into the claims, it is necessary to use "a" or "an" at the first mention of the limitation, and use "the" or said" for all subsequent mentions of the limitation.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 5 and 43-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "the end of the spacer" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 43 and 58, and claims dependent thereof, are rejected as being indefinite because examiner does not understand applicant's interpretation of the term "spaced". For examination purposes, the claim will be interpreted as a body having first and second portions, the first and second portions being spaced apart, and a platform being located between the first and second portions.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 6 and 8 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claims 6 and 8, lines 1-2, applicant positively recites part of a human, i.e. "wherein the implant is positioned between the S1 and L5 vertebrae". Thus claims 6 and 8 include a human within their scope and are non-statutory. The claim should be corrected to read --wherein the implant is adapted to be positioned between the S1 and L5 vertebrae--.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 13-26, 30-43, 47-58, and 62-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (U.S. Patent No. 5,415,659).

Lee et al. disclose an implant comprising a body (FIG.1, ref. #22), at least one hook/flange extending from the body capable of allowing the body to engage a vertebra (FIG. 1, ref. #30 and #50), a beam extending from the body (FIG. 8, ref. #90), the beam having a distal end that contacts a spinous process of another vertebra, and a device that secures the beam to the body (FIG. 8, ref. #80). The device secures the beam to the body in a plurality of positions (col. 5, lines 31-46). The distal end of the beam, the spacer, is bulbous and is round (FIG. 8, ref. #90). The spacer (FIG. 8, end part of ref. #90) has a first end for contacting a first vertebrae, a beam extending from the first end (FIG. 8, ref. #90). The beam is capable of being mounted to the base, and the base is capable of being mounted to a second vertebrae. The distal end of the beam provides a surface that is at an angle to the beam. The surface is capable of engaging L5 vertebra. The surface that is capable of spreading a contact load between a L5

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vertebra and the distal end. The distal end of the beam is capable of engaging a spinous process of a L5 vertebra. The distal end of the beam is capable of engaging a spinous process of a L5 vertebra over a conforming contact area. The distal end of the beam includes a convex surface (FIG. 8, ref. #90) that is capable of engaging a spinous process of a L5 vertebra in order to spread the load between the distal end of the beam and the spinous process of the L5 vertebrae. The beam includes an elongated aperture (FIG. 8, ref. # 92). The device extends through the aperture and can be secured to the aperture in a plurality of positions in order to position the beam relative to the body in a plurality of positions (col. 5, lines 31-46). The elongated aperture of the beam receives a post extending from the base (FIG. 8, ref. #80). A lock cooperates with the post of the base to secure the beam to the base (FIG. 1, ref. #82). The body includes a first portion and a second portion (FIG. 2, ref. #32 and #52) with a beam platform located between the first and second portions (FIG. 1, ref. #70). The beam platform is spaced from the first and second portions in order to space the beam from the first and second portions. The hook extends from the first portion and another hook extends from the second portion. The device extends from the platform. The implant comprises a device that is capable of securing the base to an S1 vertebra (FIG. 2, ref. #72). The implant is capable of being positioned between the S1 and L5 vertebrae.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-12, 27-29, 44-46, and 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (U.S. Patent No. 5,415,659).

Lee et al. disclose the claimed invention except for the implant being made from a material such as polyetheretherketone, polyaryletheretherketone, and polyetherketoneketone, polyetherketoneetherketoneketone, polyetheretherketoneketone, polyketone, polyetherketone, or titanium. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct at least a part of the device of Lee et al. from a material such as polyetheretherketone, polyaryletheretherketone, polyetherketoneketone, polyetherketoneetherketoneketone, polyetheretherketoneketone, polyketone, polyetherketone, or titanium, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See attached Form PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MCH



EDUARDO C. ROBERT
PRIMARY EXAMINER